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09/229,324	01/13/1999	YUKOH HIEI	760-262P	7108

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*HL*

## Office Action Summary

**Application No.**

09/229,324

**Applicant(s)**

HIEI ET AL.

**Examiner**

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-54 is/are pending in the application. ✓
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date January 1999
- ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date 2/22/05
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response, dated 11 August 2004, which has been entered.
2. The finality of the last Office action is withdrawn, in view of the following new grounds of rejection. The Office regrets any inconvenience to the Applicant.
3. Claims 35-54 are pending, and are examined in this action.

### ***Information Disclosure Statement***

4. A signed copy of the IDS submitted 13 January 1999 is attached.

### ***Claim Rejections - 35 USC § 112, first paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 35-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the preculture of maize explants in an auxin-containing dedifferentiating medium for 1-6 days prior to incubation with Agrobacterium, does not reasonably provide enablement for claims broadly drawn to Agrobacterium transformation of regenerable maize tissue incubated for an unspecified duration on an auxin-containing medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The claims are broadly drawn to a method for producing a fertile transgenic maize plant wherein any regenerable maize cells are precultured for any duration, including one second<sup>on</sup> an auxin-containing medium, prior to *Agrobacterium* transformation, followed by regeneration of a fertile maize plant therefrom.

In contrast, the specification only provides guidance for the obtention of whole, fertile transgenic maize embryo or meristem explants which have first been precultured for 1-6 days prior to *Agrobacterium* transformation. No guidance is provided for the regeneration of any transformed plant, fertile or otherwise, from maize tissue, subjected to any other preculture regimen.

Whole plant regeneration in maize is unpredictable and largely limited to somatic embryogenesis from embryogenic callus or suspensions. Green et al (1975, *Crop Science* 15: 417-421, cited by Applicants) teach the general recalcitrance of maize to whole plant regeneration, and the failure of explants such as shoots, flowers and mature embryos to produce callus capable of regenerating whole plants (see, e.g., page 417, column 1, penultimate paragraph). Green et al (1975) ultimately obtained success by utilizing portions of immature maize embryos as the source of callus (see, e.g., page 417, column 2, top paragraph).

Green (1982, *Proc. Fifth International Congress of Plant Tissue and Cell Culture*, pages 107-108, cited by Applicants) teaches that embryogenic maize callus has the advantages of easy visual observation and extensive duration of regenerability in culture (see, e.g., page 107, first, second and fourth paragraphs).

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Vasil et al (1987, Theoretical and Applied Genetics 73: 793-798) reiterate maize's recalcitrance to regeneration in their teaching that protoplasts of an embryogenic maize culture rarely yielded callus themselves, and that the resultant callus yielded somatic embryos but were unable to produce whole plants (see, e.g., page 793, Abstract and penultimate paragraph of column 1).

Rhodes et al (1988, BioTechnology 6: 56-60, cited by Applicants) teach that even when whole maize plants were produced from protoplasts which had formed embryogenic callus, the plants were sterile (see, e.g., paragraph bridging pages 58 and 59).

In addition, maize has historically been recalcitrant to Agrobacterium mediated transformation, due to host range problems, lack of wounding response, and lack of cell competence, as taught by Potrykus (1990, BioTechnology 8: 535-542, on page 538, column 2, ¶ 3, cited by Applicants).

Given the unpredictability, claim breadth and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for regenerating whole, transformed maize plants from explants precultured on an auxin-containing medium for a multitude of unspecified durations.

7. Claims 43 and 49 remain rejected under 35 U.S.C. 112, first paragraph, because the specification lacks sufficient evidence that the claimed biological material (pTOK162) is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 C.F.R. 1.801-1.809. If the claimed biological material

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were deposited under the provisions of the Budapest Treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest Treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of the patent.

Applicant states they are in the process of making a deposit of pTOK162 under the terms and conditions of the Budapest Treaty. This rejection will be maintained until Applicant provides a statement that a deposit will be made which satisfies 37 CFR 1.801 to 1.809, including the provision of unrestricted public availability as stated above.

The §112-1 enablement rejection of claims 43 and 49 is maintained for reasons of record.

### ***Claim Rejections - 35 USC § 102***

8. Claims 35, 36, 40, 41, 42, 44, 46, 50-52 and 54 remain rejected under 35 U.S.C. 102(b) as being anticipated by Dale et. al., Agroinfection of Wheat: inoculation of in vitro grown seedlings and embryos, Plant Science, 1989, vol. 63, pages 237-245.

Dale teaches a method of transforming wheat comprising culturing immature seedlings and immature embryos (page 238, 2<sup>nd</sup> full ¶) in a medium comprising the auxin 2, 4-D (page 238, 5th full ¶), wherein said coculturing involved incubation with an auxin-containing medium in which the Agrobacterium is suspended, and coculturing with Agrobacterium tumefaciens C58 nalR comprising a wheat dwarf virus nucleotide of interest (page 238, 5th ¶), and culturing selected tissue to obtain a transformed wheat

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plant (p. 240, final ¶). Dale also teaches the Agrobacterium comprising the Ti plasmid C58/3 (p. 240, final ¶) virB and virG genes. Accordingly, Dale anticipates the claimed invention.

Applicant's arguments filed 11 August 2004 have been fully considered but they are not persuasive. Applicant traverses that Dale et. al. do not demonstrate the presence of chromosomally integrated "transforming DNA" (Response, p. 9).

Applicant's arguments are not commensurate in scope with the claims. The claims do not require chromosomal integration. Transformation does not require chromosomal integration, only possession of heterologous DNA. Applicant further traverses that Dale et. al. do not "culture an explant...in a medium containing at least one auxin.", before contacting the plant tissue with Agrobacterium (Response, p. 10). Applicant further asserts that Dale's use of medium containing 2, 4-D is to grow tobacco cells in suspension, and that then this medium is mixed with the Agrobacterium used for the transformation. Applicant's argument is unpersuasive. Dale's inoculation of tissue using Agrobacterium suspended in an auxin-containing medium constitutes instantaneous preculture.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 35-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,591,616. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus claims of patent 5,591,616 and the species claims of the instant application are obvious over each other.

Claims 35-49 are drawn to a method for transforming a monocot plant comprising: i) culturing an explant of said monocot plant, or a tissue isolated from said explant, in a medium comprising at least one auxin to obtain a cultured tissue; ii) coculturing the cultured tissue from step i) with an *Agrobacterium* comprising a polynucleotide of interest, iii) selecting cultured tissue into which the polynucleotide of interest has been introduced; and , iv) culturing the selected tissue on a regeneration medium to obtain a transformed monocot plant. Claims 50-54 are drawn to a method for transforming a tissue of a monocot plant comprising: i) culturing an explant of an



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innature tissue of a monocot plant on a medium comprising at least one auxin wherein said medium induces dedifferentiation of the cells of the explanted tissue to obtain a dedifferentiated cultured immature tissue, ii) contacting the dedifferentiating or dedifferentiated cultured immature tissue with cells of Agrobacterium bacteria that comprise a vector comprising at least one virulence gene of a Ti plasmid, a left T-DNA border, a right T-DNA border and a polynucleotide of interest located between the left T-DNA border and the right T-DNA border, thereby obtaining a transformed plant tissue.

The claims of 5,591,616 are drawn to a method of transforming a monocot callus, comprising contacting a cultured tissue of a monocot during dedifferentiation wherein said dedifferentiation is obtained by culturing an explant on a dedifferentiation-inducing medium for not less than 7 days or a dedifferentiated cultured tissue of a monocot, with a bacterium belonging to the genus Agrobacterium containing a desired gene.

The source of the callus of Patent claim 1 is an explant of a plant (step i of instant claim 1) and a dedifferentiation-inducing medium of the Patent claim 1 is the culture medium comprising an auxin (step ii of instant claim 1). Those of ordinary skill in the art know that dedifferentiation medium comprises "at least one auxin", particularly so for monocots. Patent claim 10 added to Patent claim 1, the selection step, which is step iii of instant claim 1. Patent claim 13 added to Patent claim 1 the step of regenerating a normal plant, step iv of instant claim 1. Therefore the claims of the instant case and the claims of Patent 5,591,616 are obvious over each other.

Applicant should note the Office Action of 14 August 2002, which contains a Double patenting rejection of the claims pending at that time over patent 5,591,616. In

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response to this Office Action, Applicant responded on 14 February 2003, saying that a Terminal Disclaimer was being prepared to file in the instant case. As of the current date, no Terminal Disclaimer has been filed by Applicant in this case.

This is a provisional double patenting rejection since the instant case has not been patented.

***Remarks***

11. No claims are allowed.

12. The following amendments would obviate all rejections and result in allowance of the claims:

In claim 35, line 4, insert ---for 1 to 6 days--- after "explant,".

In claims 50 and 54, line 4, insert ---for 1 to 6 days--- after "plant".

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1638 – Transgenic Plants  
8 February 2005



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